#9 Appeal Brief 4/29/03 C.P.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Robert J. Hess & Scott L. Sullivan Art Unit: 2876

Serial No.: Serial No. 09/432,469 Examiner: Le, T.

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For: PILL PRINTING AND IDENTIFICATION

BOX AF

Assistant Commissioner for Patents

Washington, D.C. 20231

BRIEF ON APPEAL

Sir:

This Brief on Appeal is submitted in triplicate.

STATUS OF CLAIMS

This is an appeal from the Examiner's final rejection of claims 1-3, 5-10, 12 and 40-50 in an Office Action dated October 8, 2002. Claims 1-3, 5-10, 12 and 40-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,266,478 (Ackley) in view of U.S. Patent No. 5,502,944 (Kraft et al.), U.S. Patent No. 5,118,369 (Shamir) and U.S. Patent No. 5,482,008 (Stafford).

STATUS OF AMENDMENT

No amendments were filed subsequent to the Office Action dated October 8, 2002.

SUMMARY OF THE INVENTION

The present invention of claim 1 is directed to a system of controlling the distribution of pills between a manufacturer and a consumer. The control is effected by the presence of a machine-readable code on a surface of each of said pills. The code conveys information relating to one of lot number, date of manufacture, date of expiration, location of manufacture, and National Drug Code number. A scanner is adapted to read the code. Further, a scanner is arranged to scan the pills during distribution between said manufacturer and said consumer so that said scanned pill may be identified.

The present inventors recognized that consumers are at risk to their health during the course of distribution of pills from a manufacturer. The manufacturer typically packages pills and labels the packages in accordance with government regulations. However, the packages pass through the hands of middlemen before the pills inside the packages reach the consumer. These middlemen may be retailers, medical facility personnel, or pill tamperers or resellers. While the pill packages are in the hands of such middlemen, anything may happen to the pills. The packages may be opened and pills switched and then repackaged. The packages may be opened by a medial facility to dispense to patients, but due to the packages containing other types of medication

being opened by the same medical facility for dispensing to others, pills inadvertently became mixed up and administered to the wrong patient.

The present invention of independent claim 1, therefore, provides a safety measure to the consumer or patient against such tampering or mix-ups by having a surface of the pills marked directly with a machine readable code which, when scanned, provides information relating to one of lot number, date of manufacture, date of expiration, location of manufacture, and National Drug Code number. This enables verification that the pills are safe and suited for the consumer/patient.

The present invention of dependent claim 2 pertains to a pill containing a drug. The pill has a surface on which is located a machine-readable code relating to one of drug information, manufacturing information, and contraindications of the drug. After recognizing that conventional pills, once removed from their associated package or container, lack any practical way to enable one to ascertain drug information, manufacturing information or contraindications of the drug just from the pills themselves, the present inventors find that marking the pills with an appropriate machine readable code permits one to scan the code to ascertain such information.

The present invention of dependent claim 3 is directed at covering the pills with a transparent layer on which is printed bar code. This avoids the need to print on the textured surface of the medication yet protect the print from being smudged or rubbed off during handling.

The present invention of dependent claims 5 and 6 is directed at the machine-readable code being a 2-dimensional, high-density bar code matrix, such as a PDF-417 type bar code. A tremendous amount of information may be encoded in the code itself,

thereby allowing a scanner to scan the code to interpret the scanned information directly, even without the need to access remote data bases to otherwise help in the interpretation of the scanned information.

The present invention of dependent claims 7 and 8 is directed at providing a code that is too difficult for the unaided human eye to notice or interpret even if viewed. Pills with such codes become particularly well suited for use in clinical trials that use placebos and medication, because the pill codes can be machine read but be unreadable by clinical trial participants.

The present invention of dependent claim 9 is directed at a placing the machine readable code on a label that is on the body of the pill. This enables the pill to have a surface, i.e., the label surface, that may be printed upon and be better suited for receiving the print than would be the case for the pill drug surface.

The present invention of independent claim 12 provides for a process for applying a bar code to a surface of a pill. It entails: a) providing a thin sheet of biocompatible material; b) applying the code onto one surface of the thin sheet; and c) adhering the thin sheet to said surface of said pill. The result is a machine readable code applied to the surface of the pill, which provides a safeguard against mishandling or tampering as previously discussed.

The present invention of independent claim 40 is directed to a method of obtaining information concerning a pill, comprising the steps of: scanning a bar code on a surface of the pill to obtain a result; accessing a database in response to the result being obtained from the scanning of the bar code; searching the database for a correlation with the result; making an indication based on the correlation to provide

information concerning the pill; and making a determination with respect to suitability for administration of the pill based on the information.

The present invention of dependent claim 41 is directed at ascertaining from the information a likelihood as to whether the pill has been subjected to any one of tampering, unauthorized repackaging and unauthorized gray market entry.

The present invention of dependent claim 42 is directed at detecting a presence or absence of a further code that is incorporated within the bar code, and based on the detecting, making a further indication.

The present invention of dependent claim 43 is directed at administering the pill for consumption in response to the determination being favorable.

The present invention of dependent claim 44 is directed at comparing the information with previously retrieved information to ascertain whether a combination of pills taken one after the other may cause ill effects, the indication reflecting what was ascertained from the comparing.

The present invention of dependent claim 45 is directed at clocking a time of day as the scanning occurs; and storing in memory the time of day and the information in a manner that associates them together in response to completion of the steps of retrieving and clocking.

The present invention of dependent claim 46 is directed at making an indication that signifies whether an efficacy condition of the pill is effective or ineffective; further clocking a time of day corresponding to when the indication was made; and further storing the further clocking of the time of day in association with the efficacy condition.

The present invention of dependent claim 47 is directed at further scanning a further bar code associated with a nutritional substance to be consumed, accessing a further database in response to the further scanning of the bar code; finding a further correlation to the scanned further bar code in a further database by making a further comparison; retrieving further information from the further database that is associated with the further correlation in response to the step of finding the further correlation; and further clocking a further time of day corresponding to when the scanned further bar code of the nutritional substance was made, storing the further time of day and the further information in association with each other.

The present invention of dependent claim 48 is directed at scanning a further bar code on a container of the pill; comparing the scanned further bar code and the result for a match; making an indication of the match in response to completion of the step of comparing.

The present invention of dependent claim 49 is directed at selecting the pill to be dispensed from a dispensing machine prior to scanning, obtaining authorization information to authorize dispensing the pill from the dispensing machine, verifying the authorization information; and dispensing the selected pill provided the authorization information was verified.

The present invention of independent claim 50 is directed at an apparatus to dispense pills, comprising: a dispensing machine configured to obtain authorization information to authorize dispensing a pill, a verifier of the authorization information; a selector of the pill to be dispensed, a scanner of a bar code on the selected pill, and an access device that accesses a database containing information corresponding to the

scanned bar code, the dispensing machine being configured to dispense the selected pill provided the authorization information was verified by the verifier.

ISSUES

Did the Examiner err in rejecting claims 1-3, 5-10, 12 and 40-50 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,266,478 (Ackley) in view of U.S. Patent No. 5,502,944 (Kraft et al.), U.S. Patent No. 5,118,369 (Shamir) and U.S. Patent No. 5,482,008 (Stafford)?

GROUPING OF CLAIMS

Claims 40, 41, 43 and 44 stand or fall together. Claims 49 and 50 stand or fall together. Claim 10 stands or falls together with claim 1. The remaining claims do not stand or fall together, but are patentable in their own right.

ARGUMENT

The final Office Action fails to make out a prima facie case of obviousness in spite of the following assertions that it makes (identified in bold on pages)

It would have been obvious to print a bar code for identifying information relating to the pill on the surface of the pill.

This assertion is a conclusory statement.

Reference to Kraft is cited as evidence that there are plenty of information relating to the pill which could be of interest or necessity to a user. Kraft also discloses [sic] the need of product identification including the use of bar codes, bar codes readers, databases, etc.

Such information is inconsequential with respect to pills that have left their containers and can no longer be correlated with their containers to ascertain what the containers say they contain. Further, in view of tampering and pill substituting concerns, there is no assurance that the pills in a properly marked container are the original pills packaged in the container by the manufacturer or are in conformance with information stated on the container.

Reference to Shamir is cited as evidence showing it is possible to use of a micro-bar code to label small product other than an IC die/chip.

A skilled artisan would understand from Shamir that the "small products" it envisions are merely equivalents to IC die/chip. Pills are simply not analogous products. In view that Shamir is directed to imprinting on IC die/chips, such constitutes non-analogous art and is not properly relied upon by the patent examiner to justify an obviousness rejection.

Reference to the Stafford is further cited as evidence showing that it is actually possible to print a bar code on the surface of an object having the approximate shape of a typical pill and/or capsule.

Stafford places a bar code on its bolus to help identify the transponder inside. Neither Ackley, Kraft et al, or Shamir pertain to transponder identification so there is neither motivation nor incentive to apply its teaching to modify Ackley. Further, unlike the present invention, Stafford is not concerned with administering the wrong bolus/transponder that may give rise to a health or safety issue, because any bolus/transponder administered would be correct.

From the comprehensive teachings of the prior art of record, it has been determined that it would have been obvious to provide a bar code on a surface of a pill for the purpose of product identification thereof. The modification is well within the skill levels and expectations of an ordinary skilled artisan at the time the invention was made.

Such a statement clearly relies on impermissible hindsight of the applicant's disclosure. The specific "comprehensive teachings of the prior art of record" as it may pertain to the claimed invention is never revealed in the Office Action. Indeed, no effort at all was made to compare the claim language itself with any of the prior art teachings. In the

absence of such a comparison, the finding of obviousness is necessarily unsubstantiated and without justification. Further, the Office Action makes no effort at even identifying what those skill levels are of an ordinary skilled artisan at the time the invention was made.

Regarding claim 3, see the discussions above. Specifically, Stafford disclose the concept of having a transparent cover for protecting the inner core 2 and the bar code 15 from [sic] being damaged. Following this teaching, it would have been obvious to incorporate the use of a protective layer for protecting the surface of the pill and the bar code from being damaged. The modification is merely a design consideration which would have been well within the skill levels and expectations of an ordinary skilled artisan.

Such is a clear misreading of claim 3. Claim 3 calls for a transparent layer having an inner and outer surface. The bar code is arranged on the inner surface and visible through the transparent layer. In Stafford, the bar code is on the outer surface of a inner core 2 and the inner core 2 is fitted within a transparent shell 3. Since the bar code is not placed on the inner surface of the transparent shell, but rather on the outside surface of the shell 3 and the outside surface of the inner core 3, Stafford does not render obvious claim 3. Further, by printing on the underside of the transparent layer, any problems that might otherwise arise due to difficulties in printing on a textured drug surface are avoided. Note Fig. 1 of Stafford and the discussion at col. 6 lines 4-5 and 16-18.

Regarding claim 6-10, 12, 40-50, see the discussions above. Specifically, the various features of the claims, i.e. 2D bar code, PDF 47 bar code, UPC bar code, the step of administering the drug to a user, the step of warning a user based on dosage information, etc. are merely the variations in designs and/or intended applications of a pill product identification system. Without any specific, unexpected result, it would have been obvious to incorporate these features in the system as taught, as has been discussed above. The modifications are merely within the skilled level and expectations of an ordinary skilled artisan.

The Examiner's claim analysis for claims 6-10, 12, 40-50 fails to properly apply the test for obviousness and thus the rejection should be overturned on this basis alone. Such an analysis clearly is at odds with MPEP 2143, which provides:

> 2143 Basic Requirements of a Prima Facie Case of Obviousness
>
> To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.
>
> The teaching or suggestion to make the claimed combination and the reasonable

expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Here, the Office Action fails to even comment on any suggestion or motivation for making the hypothetical combination. In addition, whether or not the four patent documents being applied in the rejection reveal various concepts, they fail to demonstrate any reasonable expectation of attaining the subject matter recited in the rejected claims. Further, the Office Action provides no claim language analysis with the hypothetical modification of patent teachings and therefore fails to consider all the claim limitations as recited by the rejected claims. The obviousness rejection clearly uses the applicant's disclosure to impermissibly pick and choose various features in the prior art in an effort to yield the present invention. In doing so, the effort blatantly falls short of yielding the claimed subject matter.

In an effort to overcome this deficiency, the Office Action characterizes the subject matter of the rejected claims as "merely the variations in designs and/or intended applications of a pill product identification system". The contention is flawed for many reasons. First, the regulations do not permit an examiner to bypass the prima facie case for obviousness by asserting that the claimed invention is merely a variation in design and/or intended application. MPEP 2143. Second, the Office Action's analysis fails to make a comparison between all the claim language and the hypothetical combination of prior art. Third, the patent statutes do not require there be an "specific, unexpected result" for an invention to be patentable and thus the Examiner's

requirement that such be present is contrary to the regulations.

Instead, MPEP 2141 provides:

> STANDARD OF PATENTABILITY TO BE APPLIED
>
> IN OBVIOUSNESS REJECTIONS
>
> Patent examiners carry the responsibility of making sure that the standard of patentability enunciated by the Supreme Court and by the Congress is applied in each and every case. The Supreme Court in Graham v. John Deere, 383 U.S. 1, 148 USPQ 459 (1966), stated:
>
> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquires may have relevancy. . . This is not to say, however, that there will not be difficulties in applying the nonobviousness test. What is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context. The difficulties, however, are comparable to those encountered daily by the courts in

such frames of reference as negligence and scienter, and should be amenable to a case-by case development. We believe that strict observance of the requirements laid down here will result in that uniformity and definitiveness which Congress called for in the 1952 Act.

Office policy is to follow Graham v. John Deere Co. in the consideration and determination of obviousness under 35 U.S.C. 103. As quoted above, the four factual inquires enunciated therein as a background for determining obviousness are as follows:

(A) Determining the scope and contents of the prior art;

(B) Ascertaining the differences between the prior art and the claims in issue;

(C) Resolving the level of ordinary skill in the pertinent art; and

(D) Evaluating evidence of secondary considerations.

The Supreme Court reaffirmed and relied upon the Graham three pronged test in its consideration and determination of obviousness in the fact situations presented in Sakraida v. Ag Pro, Inc., 425 U.S. 273, 189 USPQ 449, reh'g denied, 426 U.S. 955 (1976) and Anderson's-Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57, 163 USPQ 673 (1969). In each case, the Court discussed whether the claimed combinations produced a "new or different function" and a "synergistic result," but it clearly decided whether the claimed inventions were nonobviousness on the basis of the three-way test in Graham. Nowhere in its decisions in these cases does the Court state that the "new or

different function" and "synergistic result" tests supersede a finding of nonobvious or obviousness under the Graham test. Accordingly, examiners should apply the test for patentability under 35 U.S.C. 103 set forth in Graham.

As concerns the relevance of the four patent documents to claims 6-10, 12, 40-50, the Office Action fails to render an analysis in compliance with the four Graham factors (see page 2 of the Office Action). No effort was made to determine to scope and contents of the prior art as it may pertain to the subject matter of claims 6-10, 12, 40-50. While some effort was made to ascertain differences between the prior art and the claims at issue, the failure to conduct a claim element by claim element analysis demonstrates the lack of making a rigorous comparison and thus the failure to comply with the Graham criteria. Finally, no effort was made by the Office Action to resolve the level of skill in the pertinent art. Even without showing secondary considerations, the Office Action on its face fails to comply with the first three Graham factors and thus warrants immediate withdrawal of the claim rejection.

In sum, the Office Action failed to abide by the Graham criteria on the basis that the claimed invention is somehow "merely design variations and/or intended applications of a pill product identification system". Finding an invention obvious based on a contention of "design variations" and/or "intended applications" is a fictitious contention that is not recognized by any statute, rule or regulation pertaining to obviousness. It certainly does not fit into any of the four Graham criteria and thus is necessarily improper.

When all the above arguments were presented to the Examiner, the Examiner responded as follows in an Office Action dated October 8, 2002:

In the Office Action dated 4/8/2002, the examiners cited 4 references including one primary reference and three supporting references for his grounds of rejection on the claim. The examiner also provides a statement for each reference in order to establish the scope and contents of these cited prior art references. The difference between the prior art of record and the claimed invention is clearly stated. The motivation statements are also included to establish the reasons why each supporting reference is being used in supporting the proposed combination For these reasons, the examiner disagrees with applicant's statement that the examiner's obvious statements set forth in the Office Action is merely a 'conclusory statement'.

In the Office Action, the primary reference (Ackley), is cited as evidence showing the needs for marking pills. Though (sic) Ackley is silent about the use of a bar code to label a pill, the missing feature is strongly suggested and evidenced by Kraft, Shamir, and Stafford.

Specifically, the examiner first cited Kraft as evidence showing that a bar code could be used in place of the printed indicia on the pill as taught by Ackley. Reference to Shamir, and Stafford are both cited as evidence showing that labeling an object with the size and shape of a pill is possible. Specifically, Shamir discloses a 2D bar code and discloses that the bar code could be used to label any small object (which of course include a pill, or capsule). Reference to

Stafford is cited as evidence showing the use of bar code for labeling a capsule shaped object (i.e., the transponder as cited in the Office Action). According to the examiner, the Office Action not only citing that there are real need [sic] to label the pills, the capsule; but also providing evidence that more information (in the form of a bar code) could be printed on the surface of the pills or capsules.

MPEP 2143.01 provides:

FACT THAT REFERENCES CAN BE COMBINED OR MODIFIED IS NOT SUFFICIENT TO ESTABLISH PRIMA FACIE OBVIOUSNESS

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)

The only "desirability" that the Examiner points to is his contention that the prior art he relies on shows there is a "real need" to label pills. The rest of the contention uses words such as "could be used in place of ...", "labeling ... is possible", "could be used to label", "showing the use of bar code for labeling ..." and "could be printed on the surface". Desirability of the combination is not shown by what "could be" or "is possible". As for showing the "real need" to label pills, an issue more in point is to show the "real need" to label pills with a bar code, because pills are labeled conventionally insofar as they are marked with a brand name, for instance, as mentioned in Ackley.

Merely labeling pills with a corporate brand name misses out on an opportunity to inform the would be user of the pill about a considerable amount of pertinent information

pertaining to the pill. For instance, providing the lot number, date of manufacture, date of expiration, location of manufacture, and National Drug Code number (see claim 1) can tell a lot about the pill to the user or about how safe it is to take the pill and can tell a lot to authorities trying to track down pill tampering or resellers. Just knowing the date of expiration, for instance, can help verify that pills within a container are still potent and haven't been replaced by pills whose expiration has passed. Further, when a consumer needs to take a variety of pills and stocks up on them, knowing the expiration date of the actual pill is useful particularly where the consumer has removed the pills from their container and filled a pill timer device, because if the container is refilled before all the pills are taken, perhaps the pills at the bottom remain in the pill timer device too long. Medical facilities may face similar issues about expiration if they purchase pills in bulk and store them for future dispensement.

Providing drug information, manufacturing information, and contraindications of the drug (see claim 2) is useful to the would be pill taker or medical facility pill administrator to help verify that the pill is safe to be administered. For instance, drug information would avoid the potential for pill mix-ups, particularly where different types of pills visually resemble each other but contain different types of drugs. Manufacturing information would help in the tracking of the pill to verify from where it originated to avoid counterfeits. Information pertaining to contraindications of the drug is useful for alerting the would be pill taker of the potential health risk if other types of drugs are taken at the same time.

Of the four citations, only Stafford marks a bolus container with a bar code, but the information such a bar code is to convey pertains to a transponder within the bolus.

Such information would be of no value to either consumers or administrators of pills that contain drugs or medication because no transponder is used. The remaining references reveal nothing about marking pills with bar code and thus leave consumers and pill administrators in the dark when it comes to trying to figure out information about a pill in the event the pill can no longer be correlated with its container. As such, claims 1 and 2 are not rendered obvious by the combination.

Claim 3, which pertains to the marking a bar code under a transparent layer, recognizes the risk that pill handling may have on maintaining the readability of the bar code, because it protects the bar code from being smudged or worn away. Such is not a concern for pill markings that are merely a corporate brand name, because the brand name contains no critical information about the pill that might be useful to the would be consumer or pill administrator. Thus, neither Ackley, Kraft nor Shamir render obvious such a concept. Although Stafford reveals a transparent cover for protecting the inner core 2, the bar code is not applied to the transparent cover, in contrast to the recitation of claim 3 that calls for the code to be located on the inner surface of the protective layer. Although both techniques enable one to see the bar code through a transparent layer or cover while protecting the bar code, arranging the bar code on the inside surface of the transparent layer as in claim 3 provides the dual advantages of printing on a surface is more amenable to receiving print than is the case where medication is to be printed upon directly. Indeed printing a bar code on a transparent layer, for instance, may be easier to accomplish than printing on the surface texture of the contents of the pill or capsule because surface texture may not be rough or powdery. Indeed, by printing instead on the inner surface of a transparent layer, the print should be clear and

the layer may thereafter encapsulate about or be injected with the medication contents while the imprinted bar code remains intact.

Claims 5 and 6 refer to types of bar codes that may contain a considerable amount of information that may be scanned. The encoded information itself may be interpreted directly to reveal pertinent information even without resorting to accessing a central data base to interpret the encoded information. Clearly, none of the four citations provide for such a capability because of the limitations inherent for the bar codes they employ.

Claims 7 and 8 pertain to presenting the bar code in a manner that renders them virtually impossible to distinguish one from the other with the unaided human eye. Such is of benefit for clinical trials in which placebos and medication are taken by participants but the administrators want a technique that enables on site verification of which pill is which (by using a machine scanner) and yet prevent the participant from figuring out which is which over time. Under conventional clinical trial testing procedures, participants have observed differences in the pills taken by fellow participants and insisted they be given the same when their fellow participants show improvement in their symptoms while they do not (because they suspect they are taking a placebo). As a consequence, the integrity of the clinical trial results may be lost without sufficient placebo takers. None of the four citations even address clinical trials.

Claim 9 provides for printing a machine readable code on a label to be applied to a pill, rendering the manufacturing process easier where there are difficulties printing directly on the pill surface itself due to its surface structure. However, printing on the surface of a label would not pose the same difficulties so merely attaching the label to

the pill would accomplish the same end result in effect as imprinting directly on the pill.

Claim 12 pertains to a method of applying a bar code to a surface of a pill and should be deemed patentable for many of the same reasons as claim 3 although claim 12 does not recite "transparent". The invention of claim 12 recognizes it is easier to print on a biocompatible layer than on the surface texture of the pill itself, such as when the surface texture of the pill is rough or powdery.

Claim 40 is directed at a method of obtaining information concerning a pill and includes the step of scanning a bar code on a surface of the pill to obtain a result, accessing a database in response to the result being obtained from the scanning of the bar code; searching the database for a correlation with the result. Claim 40 further recites making an indication based on the correlation to provide information concerning the pill; and making a determination with respect to suitability for administration of the pill based on the information.

Ackley and Kraft fail to teach about bar codes on pill surfaces, Shamir fails to teach about pills and Stafford fails to teach about pills or capsules containing medication. Thus, none reveal scanning a bar code on a surface of a pill and thus would neither access nor search a database in response to the scanning and thus would not reveal making an indication or a determination as a result of the accessing and searching.

Claim 42 is directed at detecting a further code within the bar code. Such is advantageous for security purposes because the presence of the further code makes counterfeiting more difficult. None of the four citations even remotely consider this.

Claims 45-47 pertain to clocking the scanning to assist in record keeping for

patient monitoring. This makes it simple to keep track of a patient's intake because after the pill bar code is scanned, the time of day is recorded so information as to when the medication was taken is stored at the time of scanning for future reference. A physician or patient checking when the bar code was last scanned would thus be able to associate the pill with the time it was taken. Such an association between scanning bar code and the time of day or the advantages from such association with respect to patient record keeping is not disclosed by any of the four citations.

Claim 48 provides for a technique to quickly check for product tampering: if the bar code information on the pill container does not match the bar code information on the pills, one might suspect product tampering or putting pills back in the container that were not originally there. None of the four citations recognize such a possibility.

Claims 49 and 50 provide for a technique and device to dispense pills from a dispensing machine only upon receiving proper authorization to do so. This limits access to pills in the dispensing machine that have bar codes on them. Such a security arrangement is not envisioned by the cited references with respect to bar coded pills.

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APPENDIX OF CLAIMS

Claims 1-3, 5-10, 12, 40-50

1. A system of controlling the distribution of pills between a manufacturer and a consumer, said system comprising:

a machine-readable code on a surface of each of said pills, said code conveying information relating to one of lot number, date of manufacture, date of expiration, location of manufacture, and National Drug Code number;

and

a scanner adapted to read said machine-readable code of said at least one of said pills; and

a scanner arranged to scan said at least one of said pills during distribution between said manufacturer and said consumer so that said scanned pill may be identified.

2. A pill containing a drug and having a surface, said pill comprising:

a machine-readable code located on said surface, said code relating to one of drug information, manufacturing information, and contraindications of the drug.

3. A pill according to claim 2, wherein said pill includes a transparent layer defining an outer surface and an inner surface, said code being located on said inner surface so that said code may be machine-read through said transparent layer.

5. A pill according to claim 2, wherein said machine-readable code is a 2-dimensional, high-density bar code matrix.

6. A pill according to claim 6, wherein said 2-dimensional, high-density bar code matrix is a PDF-417 type bar code.

7 A pill according to claim 1, the code having a coded pattern that is too difficult for an unaided human eye after glancing the coded pattern to discern differences within the coded pattern that may distinguish the coded pattern from others of the same type.

8. A pill as in claim 7, wherein the coded pattern lacks alphanumeric characters.

9. A pill as in claim 8, further comprising a label on which is printed the machine readable code, said label being on a body of the pill.

10. A pill as in claim 1, wherein the pill is any one of a tablet and capsule.

12. A process for applying a bar code to a surface of a pill, comprising the steps of:

a) providing a thin sheet of biocompatible material;

b) applying said code onto one surface of said thin sheet; and

c) adhering said thin sheet to said surface of said pill.

40. A method of obtaining information concerning a pill, comprising the steps of:

scanning a bar code on a surface of the pill to obtain a result;

accessing a database in response to the result being obtained from the scanning of the bar code;

searching the database for a correlation with the result;

making an indication based on the correlation to provide information concerning the pill; and

making a determination with respect to suitability for administration of the pill based on the information.

41. A method as in claim 40, further comprising:

ascertaining from the information a likelihood as to whether the pill has been subjected to any one of tampering, unauthorized repackaging and unauthorized gray market entry.

42. A method as in claim 40, further comprising the step of detecting a presence or absence of a further code that is incorporated within the bar code, and based on the detecting, making a further indication.

43. A method as in claim 40, comprising the steps of:

in response to the determination being favorable, administering the pill for consumption.

44. A method as in claim 40, further comprising the step of:

comparing the information with previously retrieved information to ascertain whether a combination of pills taken one after the other may cause ill effects, the indication reflecting what was ascertained from the comparing.

45. A method as in claim 40, further comprising the steps of:

clocking a time of day as the scanning occurs; and

storing in memory the time of day and the information in a manner that associates them together in response to completion of the steps of retrieving and clocking.

46. A method as in claim 45, further comprising the steps of:

making an indication that signifies whether an efficacy condition of the pill is effective or ineffective;

further clocking a time of day corresponding to when the indication was made; and

further storing the further clocking of the time of day in association with the efficacy condition.

47. A method as in claim 46, further comprising the steps of further scanning a further bar code associated with a nutritional substance to be consumed,

accessing a further database in response to the further scanning of the bar code;

finding a further correlation to the scanned further bar code in a further database by making a further comparison;

retrieving further information from the further database that is associated with the further correlation in response to the step of finding the further correlation; and

further clocking a further time of day corresponding to when the scanned further bar code of the nutritional substance was made, storing the further time of day and the further information in association with each other.

48. A method as in claim 40, further comprising the steps of

scanning a further bar code on a container of the pill;

comparing the scanned further bar code and the result for a match;

making an indication of the match in response to completion of the step of comparing.

49. A method as in claim 40, further comprising:

prior to scanning, selecting the pill to be dispensed from a dispensing machine,

obtaining authorization information to authorize dispensing the pill from the dispensing machine,

verifying the authorization information; and

dispensing the selected pill provided the authorization information was verified.

50. An apparatus to dispense pills, comprising:

a dispensing machine configured to obtain authorization information to authorize dispensing a pill,

a verifier of the authorization information;

a selector of the pill to be dispensed,

a scanner of a bar code on the selected pill, and an access device that accesses a database containing information corresponding to the scanned bar code, the dispensing machine being configured to dispense the selected pill provided the authorization information was verified by the verifier.

AF/2876

PTO/SB/21 (03-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/432,469
Filing Date	November 3, 1999
First Named Inventor	Robert J. Hess
Art Unit	2876
Examiner Name	Le, T.
Attorney Docket Number	

Total Number of Pages in This Submission: 83

ENCLOSURES (*Check all that apply*)

- [x] Fee Transmittal Form
  - [x] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
- [ ] After Allowance Communication to a Technology Center (TC)
- [ ] Appeal Communication to Board of Appeals and Interferences
- [x] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [ ] Other Enclosure(s) (please Identify below):

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual	Robert J. Hess
Signature	Robert J. Hess
Date	March 2003

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date: March 25, 2003

Typed or printed	Robert J. Hess		
Signature	Robert J. Hess	Date	3-25-2003

PTO/SB/17 (01-03)
Approved for use through 04/30/2003. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL for FY 2003

Effective 01/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 215

Complete if Known	
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METHOD OF PAYMENT *(check all that apply)*

☒ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☐ Deposit Account:

Deposit Account Number

Deposit Account Name

The Commissioner is authorized to: *(check all that apply)*

☐ Charge fee(s) indicated below ☐ Credit any overpayments

☐ Charge any additional fee(s) during the pendency of this application

☐ Charge fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	750	2001	375	Utility filing fee	
1002	330	2002	165	Design filing fee	
1003	520	2003	260	Plant filing fee	
1004	750	2004	375	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

	Extra Claims		Fee from below		Fee Paid
Total Claims		-20** =		X	=
Independent Claims		- 3** =		X	=
Multiple Dependent					=

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	84	2201	42	Independent claims in excess of 3
1203	280	2203	140	Multiple dependent claim, if not paid
1204	84	2204	42	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	55
1252	410	2252	205	Extension for reply within second month	
1253	930	2253	465	Extension for reply within third month	
1254	1,450	2254	725	Extension for reply within fourth month	
1255	1,970	2255	985	Extension for reply within fifth month	
1401	320	2401	160	Notice of Appeal	160
1402	320	2402	160	Filing a brief in support of an appeal	
1403	280	2403	140	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,300	2453	650	Petition to revive - unintentional	
1501	1,300	2501	650	Utility issue fee (or reissue)	
1502	470	2502	235	Design issue fee	
1503	630	2503	315	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	750	2809	375	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	750	2810	375	For each additional invention to be examined (37 CFR 1.129(b))	
1801	750	2801	375	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 215

SUBMITTED BY				(Complete *if applicable*)	
Name (Print/Type)	Robert J. Hess	Registration No. (Attorney/Agent)	32,139	Telephone	212 649-4700
Signature	Robert Hess			Date	3-25-2003

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